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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
COTTON, ABIGAIL MANDA	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/505,178	PINZA, MARIO	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/31/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-8 are pending in the application.

Priority

Applicant's claim of foreign priority to ITALY MI2002A000986 is acknowledged.

Specification

Applicant's disclosure is objected to because the sections corresponding to the Background, Summary and Detailed Description of the Invention are not indicated as such. Appropriate correction, namely the insertion of section headings where appropriate, is required.

Applicant is reminded of the following proper form of the specification:

Content of Specification

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

Or alternatively, Reference to a "Microfiche Appendix": See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.

(e) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(f) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the

invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(g) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(h) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(i) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(j) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

(k) Sequence Listing, See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Claim Objections

Claims 4-8 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, for failing to further limit the subject matter of claim 1. Claim 8 recites an intended use of the composition claimed in independent claim 1, namely that the composition is intended for use in the treatment of gingivitis, glossitis, stomatitis, aphthae, etc. Claim 8 does not further limit the formulation of the claim from which it depends, as it does not recite any further chemical or structural features of the formulation. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by the article "Preparation and Characterisation of a Range of Diclofenac Salts" by O'Connor et al, International Journal of Pharmaceutics, having a date of receipt of October 3, 2001.

O'Connor et al. teaches characterizing different salts of diclofenac, including tris(hydroxymethyl)aminomethane salt (tromethamine) (see abstract, in particular.) O'Connor et al. teaches formulating an aqueous solution of the tromethamine salt of diclofenac (DTRIS), having a pH of 7.13 and a saturated solubility of about 3.95 mM (see page 172, paragraph bridging right and left hand columns, in particular), which is equivalent to about a 0.16% w/w solution of the diclofenac tromethamine salt and thus meets the limitation of the claim.

It is respectfully pointed out that the recitation that the composition is for "topical treatment of oropharyngeal cavity disorders" in claim 1 has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are

able to stand alone. See *in re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152 88 USPQ 478, 481 (CCPA 1951.)

Furthermore, it is respectfully noted that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963.) Thus the intended uses recited in claim 8, namely that the composition is used in the treatment of "gingivitis, glossitis, stomatitis" and other disorders, is not afforded patentable weight.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-4 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,626,838 to Cavanaugh, Jr., issued May 6, 1997, in view of the

article "Preparation and Characterisation of a Range of Diclofenac Salts" by O'Connor et al.

Cavanaugh, Jr. teaches methods for prevention or treatment of primary and recurring squamous cell carcinoma by topical administration to the oral cavity or oropharynx of an effective amount of an NSAID (see abstract, in particular.) Cavanaugh, Jr. teaches that it is known to topically administer NSAIDs such as diclofenac for the treatment of various diseases and conditions (see column 1, lines 44-65, in particular.) Cavanaugh, Jr. teaches that the composition can be in the form of a toothpaste, mouthwash, mouthspray and the like (see column 3, lines 40-42, in particular.) Cavanaugh, Jr. teaches that water can comprise from 2 to 99% of the compositions, such as from about 45% to about 95% of a mouthwash (see column 5, lines 44-56, and Examples 3, 4 and 5 in particular.) Accordingly, Cavanaugh, Jr. teaches an aqueous composition having an NSAID.

Cavanaugh, Jr. furthermore teaches that the concentration of the NSAID in the solution is selected to provide an effective concentration of the NSAID solution in the mouth in contact with the oral cavity, and may be selected with respect to factors such as the dilution that occurs in the mouth from saliva (see column 5, lines 1-20, in particular.) Cavanaugh, Jr. teaches that a suitable concentration of the NSAID may generally be from about 0.02% to about 4% (see column 5, lines 10-15, in particular.)

Cavanaugh, Jr. furthermore teaches that a suitable pH of the composition can be from about 2 to about 9 (see column 5, lines 24-27, in particular.)

Regarding claim 3, Cavanaugh, Jr. teaches that sweetening agents such as saccharine salts and acesulfame (see column 6, lines 40-48, in particular.)

Regarding claim 4, Cavanaugh, Jr. teaches that the composition can comprise preservatives such as benzoates and exemplifies compositions with sodium benzoate (see column 7, lines 5-15, and Examples 3, 4 and 5, in particular.)

Regarding claim 6, Cavanaugh, Jr. teaches that the composition can comprise flavoring agents, such as menthol and wintergreen oil (see column 6, lines 32-39, in particular.)

Regarding claim 7, Cavanaugh, Jr. exemplifies compositions with FD&C Blue (see Examples 3, 4 and 5, in particular.)

Cavanaugh, Jr. does not specifically teach providing a composition having an NSAID that is diclofenac in the percent concentration and pH ranges recited in the claim.

O'Connor is applied as discussed for claims 1 and 8 above. O'Connor et al. teaches that diclofenac is a potent anti-inflammatory drug that is therapeutically used (see page 164, paragraph bridging right and left hand columns, in particular.) O'Connor et al. furthermore teaches the preparation of the Tris(hydroxymethyl)aminomethane salt of diclofenac (DTRIS), which is the tromethamine salt of diclofenac (see pages 164-166, in particular.) As discussed for claims 1 and 8 above, O'Connor et al. teaches that the tromethamine salt of diclofenac has a solubility in water that meets the concentration limitation of the claim, and at a pH within the claimed range (see Table 3, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have been motivated to provide the tromethamine diclofenac salt of O'Connor et al. at a weight percent and pH within the recited range, in the oral treatment composition of Cavanaugh, Jr., because Cavanaugh, Jr. teaches that the composition comprises an effective amount of an NSAID to treat oral disorders, and O'Connor et al. teaches that diclofenac is a NSAID capable of treatment and can be formulated in a percent by weight and pH that meet the limitations recited in the claim, which parameters are furthermore within the general concentration % and pH parameters specified as suitable by Cavanaugh, Jr. Accordingly, one of ordinary skill in the art would have been motivated to provide the diclofenac salt taught by O'Connor et al. and at the wt% and pH recited in the claims, with the expectation of providing a composition for treating oral disorders having a suitable formulation of the diclofenac NSAID.

Furthermore, regarding the specific concentration percentage recited in claim 2, it is considered that one of ordinary skill in the art would have found it obvious to vary the pH and concentration of the diclofenac tromethamine salt to obtain a desired effective amount of the NSAID, particularly in light of the teachings of Cavanaugh, Jr. and O'Connor et al. For example, one of ordinary skill would have found it obvious to vary the concentration to arrive at a desired effective concentration with regards to any dilution effects from saliva, as taught by Cavanaugh, Jr, and to vary the concentration to achieve solubility of the diclofenac tromethamine salt, as taught by O'Connor et al. It is furthermore noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cavanaugh, Jr. and O'Connor et al, as applied to claims 1-4 and 6-8 above, and further in view of U.S. Patent No. 5,028,413 to Bianchi et al.

Cavanaugh, Jr. and O'Connor et al. are applied as discussed above. The references teach a topical composition for oral treatment comprising an aqueous solution of tromethamine salt of diclofenac with the recited concentration and pH limitations. Cavanaugh, Jr. furthermore teaches that it may desirable to provide a fluoride ion source in the composition as an anticaries agent (see column 7, lines 45-59, in particular.)

Cavanaugh, Jr. and O'Connor et al. do not specifically teach providing a gelling agent comprising a block copolymer of polyethylene glycol and polypropylene glycol.

Bianchi et al. teaches an aqueous-based dentrifice composition containing a polyoxyethylene polyoxypropylene block copolymer gelling agent (see abstract, in particular.) Bianchi et al. teaches that the composition having the block copolymer provides enhanced lubricating properties, and allows a high degree of fluoride delivery to the teeth (see column 2, lines 4-11.)

Accordingly, one of ordinary skill in the art would have found it obvious at the time the invention was made to provide the gelling agent of Bianchi et al. in the composition of Cavanaugh, Jr. and O'Connor et al, with the expectation of achieving a composition suitable for topical treatment of oral disorders, and having improved lubricating properties and allowing for the incorporation of the anticaries agent fluoride ion.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 8:30-5:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER